Continuous manufacturing (CM) introduces the benefits of cost efficiency, reliability and scalability for the manufacturing of biopharmaceuticals. Higher flexibility, smaller facility footprints and cost of goods benefits are advantages of this production mode. It offers high flexibility in regard of demand changes from clinical to launch and for volatile market dynamics. In combination with disposable equipment, faster time-to-market and closed processing seems feasible. Bayer’s unique CM platform consists of a series of downstream processing (DSP) unit operations through which the drug substance moves continuously and all unit operations happen more or less in parallel at the same time. The technology offers the potential to make Quality by Design (QbD) a reality (with continuously monitored process parameters and real-time feedback process control to maintain quality-indicating parameters within limits at all times, multi-variate data analysis). Individual unit operations are intelligently integrated and critical process parameters are monitored and controlled in real-time. Conditioning modules allow immediate corrective actions to be executed in an automated fashion to maintain the entire process in a state of control with low batch-to-batch variability. In addition, online sampling and testing functions provide early warning of potential excursions. By reduced manual interference this will also lead to reduction of operator errors and according deviations. Manufacturing facilities will be significantly less capital-intensive (e.g. by simpler layout) than large, traditional batch facilities as disposable technology and aseptic connections offer superior protection against bioburden ingress and other forms of contamination. The presentation also intends to illustrate comparability of CM versus batch processing in a side-by-side approach covering process information, real time analysis as well as quality data from intermediates and final drug substance of an antibody product.

Figure 1 – Bayer’s MoBiDiK technology platform for continuous downstream processing